

REMARKS

Claims 1-3, 8-25, 30-36, 37, 38 and 40-43 are presently pending in the application. Of these, claims 1, 22, 23, and 30 are independent. Claims 1, 22, 23, and 30 are presently amended and claims 5-7, 27-29, and 39 are cancelled without prejudice or disclaimer of the subject matter therein. Claims 41-42 are newly added. Reconsideration of presently pending claims is respectfully requested in light of the above amendments and the following remarks.

Compliance with §103

Claims 1-3, 5-22, and 30-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Huppert et al. (International Publication WO 03/039400) in view of Baccelli et al. (U.S. Patent No. 6,454,805) and claims 23-25 and 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Huppert in view of Baccelli and further in view of Yuan et al. (U.S. Patent No. 5,676,701).

Applicants traverse these rejections on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 1-3, 8-25, 30-36, 37, 38 and 40 as herein amended.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements is **not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art**. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does**. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added).

In the present application, a prima facie case of obviousness does not exist for claims 1-3, 8-25, 30-36, 37, 38 and 40, as previously presented or currently amended, for the reasons set forth below.

1. All Words In The Claim Must Be Considered

MPEP 2143.03 states that “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” Quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). Applicants respectfully submit that amended claim 1, reproduced below and serving as a representative claim, is patentable over the cited combination of references.

A prosthetic device for anterior-oblique insertion into an intervertebral space, comprising a first component having an outer bearing surface including an integral first flange arranged to engage a first vertebra from an anterior-oblique approach, the first flange being angled relative to the longitudinal and transverse axes of the first component, and a second component having an outer bearing surface including an integral second flange arranged to engage a second vertebra from an anterior-oblique approach, the second flange being angled relative to the longitudinal and transverse axes of the second component, and wherein the first and second components cooperate to permit articulating motion between the first and second components,

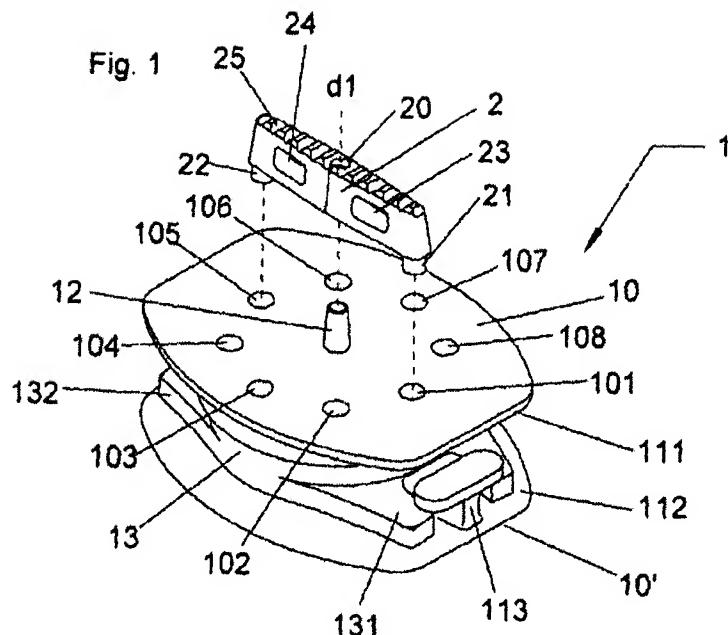
wherein the first component is triangular in shape to define first, second and third side portions, the first flange being generally parallel with one of the first, second and third side portions of the first component, and

wherein the second component is triangular in shape to define first, second and third side portions, the second flange being generally parallel with one of the first, second and third side portions of the second component.

The Office Action noted, “Huppert et al did not teach of a first component that is triangular in shape to define first, second and third side portions,” and then applied Baccelli in combination to claim 1. (Office Action, page 3).

However, as currently amended, neither Huppert, nor Baccelli alone or in combination with Huppert, teach “[an integral] first flange being generally parallel with one of the first, second and third side portions of the first [triangular shaped] component [and angled relative to the longitudinal and transverse axes]” or “[an integral] second flange being generally parallel with one of the first, second and third side portions of the second [triangular shaped] component [and angled relative to the longitudinal and transverse axes].”

Huppert discloses an implant with rectangular shaped plates 111 and 112. (Page 5, lines 9-11 and Fig. 1, reproduced below). Huppert also discloses a winglet 2 (flange), that is non-integral by design, as shown in Fig. 1.



Huppert, Fig. 1

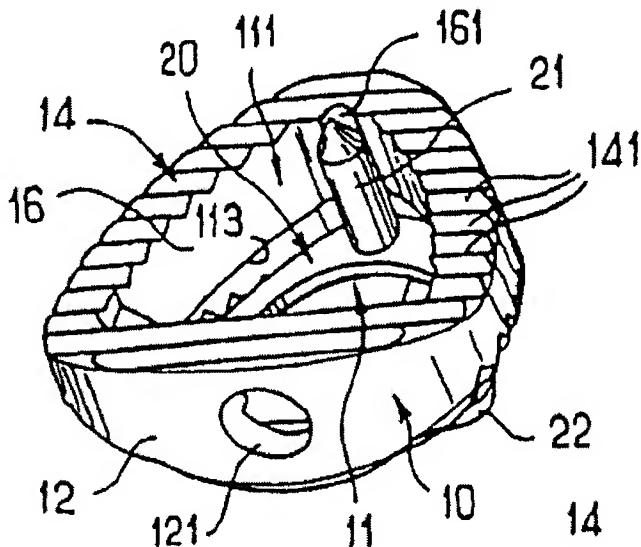
It is stated by Huppert that the winglet (or flange) 2 is “able to be positioned in a plurality of angular positions around an axis . . . the plurality of angular positions being defined by a plurality of co-operating [holes 101 to 108] prepared in the bearing face of the prosthesis and co-operating with the complementary means on the winglet.” (Page 2, lines 19-24 and page 6, lines 22-24).

It may be observed in Fig. 1 that placing winglet 2 into holes 102 and 106 would align winglet 2 on an angle relative to the longitudinal and transverse axes. However, in such an alignment, winglet 2 would fail to be generally parallel to one of the plate sides. Alternatively, if winglet 2 were aligned with 101 and 105 or with 103 and 107, then winglet 2 would *not* be on an angle relative to one of the longitudinal and transverse axes.

Thus, since Huppert teaches an adjustable flange which is aligned with respect to a rectangular plate, Huppert fails to disclose “[an integral] first flange being generally parallel with one of the first, second and third side portions of the first [triangular shaped] component [and angled relative to the longitudinal and transverse axes]” or “[an integral] second flange being generally parallel with one of the first, second and third side portions of the second [triangular

shaped] component [and angled relative to the longitudinal and transverse axes]," as required by claim 1.

Neither does Baccelli in combination with Huppert cure these deficiencies as Baccelli was cited for its teaching of "a first component that is triangular in shape to define first second and third side portions in order to insure stable bone fusion." (Office Action, page 3). Baccelli discloses a single body fusion cage, as seen in Fig. 1, reproduced below. Baccelli fails to disclose any flange as recited in the claims. Therefore, there is no suggestion in Baccelli of integral flanges aligned as recited in claim 1.



Baccelli, Fig. 1

Thus, Baccelli in combination with Huppert also fails to teach "[an integral] first flange being generally parallel with one of the first, second and third side portions of the first [triangular shaped] component [and angled relative to the longitudinal and transverse axes]" or "[an integral] second flange being generally parallel with one of the first, second and third side portions of the second [triangular shaped] component [and angled relative to the longitudinal and transverse axes]."

With respect to independent claim 23, neither does Yuan in combination with Baccelli and Huppert cure the above deficiencies as Yuan was cited solely for its teaching of "an intervertebral implant having a first articular surface forming a projection and a second articular surfaces forming a recess to allow an unrestricted motion between the first and second components." (Office Action, page 4).

Therefore, not all the words in claim 1, as amended, have been considered, as required. Since independent claims 22, 23 and 30, as currently amended, contain limitations similar to those required by claim 1, as discussed above, they should likewise be allowable. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Thus, for this reason alone, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

2. A Proposed Modification Cannot Render A Reference Unsatisfactory For Its Intended Purpose

KSR maintained the long-standing principal that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious." *KSR* at 1740. In addition, MPEP § 2143.01(V) states that there is no suggestion or motivation to make the proposed modification if the proposed modification would render the prior art invention unsatisfactory for its intended purpose.

In the present case, Huppert has as "the aim of [its] present invention," an adjustable winglet capable of being positioned in a plurality of positions determined by different surgical approaches. (Page 2, lines 3-13). Huppert states that an additional novelty of having an adjustable winglet is that it is advantageous for reducing the "number of versions to be manufactured or kept in stock." (Page 7, lines 25-28). Fixing the winglet of Huppert by making it integral and fixed on an angle as required by Applicants' independent claims, destroys the intended purpose of Huppert—namely, providing an implant with a multi-position, adjustable winglet. Huppert also teaches against plates having shapes other than that disclosed by Huppert. When discussing disadvantages of other systems, Huppert states that "the prosthesis does not have a rotary shape and must be oriented in a precise angular position around the rachis axis," implying a preference for the rounded-edge rectangular shape disclosed. (Page 2, lines 27-29 and Page 3, lines 1 and 2).

Thus, Huppert teaches against the proposed modification and is thereby not properly combinable with the proposed modifications to be applied against Applicants' independent claims.

Therefore, Applicants assert that one skilled in the art would not combine the Baccelli reference with the Huppert reference, or otherwise modify either reference, for the reasons stated.

In addition, during examination, claims must be considered as a whole, and not as separate or individual elements. (MPEP §2141.02). Therefore, “[an integral] first flange being generally parallel with one of the first, second and third side portions of the first [triangular shaped] component [and angled relative to the longitudinal and transverse axes]” or “[an integral] second flange being generally parallel with one of the first, second and third side portions of the second [triangular shaped] component [and angled relative to the longitudinal and transverse axes],” as required by claim 1 must not be separated into individual elements.

Thus, for this reason alone, the examiner’s burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claims 1-3, 8-25, 30-36, 37, 38 and 40 under 35 U.S.C. §103 should be withdrawn.

3. Independent Claim 23 And Dependent Claims 41-43

In addition to being allowable for the reasons discussed above, claim 23 recites an additional feature “wherein the first and second components each include indentation features shaped to interface with an insertion tool, the indentation features being formed in one of the first, second, and third side portions and being non-perpendicular to said one of the first, second, and third side portions.” This feature is neither taught nor suggested either in Huppert or Baccelli. Huppert lacks disclosure of any indentation features shaped to cooperate with an insertion tool and Baccelli discloses only one feature, which is perpendicular to the side it is formed into.

Therefore, the combination cited by the Examiner cannot establish a *prima facie* rejection with respect to independent claim 23. Claims 41-43 recited a similar limitation and depend from claims 1, 23, and 30 respectively. Accordingly, these claims should be allowable over the art. Applicants respectfully request that the Examiner consider and allow these claims.

Dependent claims 1-3, 8-25, 30-36, 37, 38 and 40

Dependent claims 1-3, 8-25, 30-36, 37, 38 and 40, as previously presented or currently amended, each depend from and further limit one of the independent claims 1, 23 and 30 and therefore are deemed to be patentable over the cited art.

In addition, the Office Action stated, “[w]ith respect to claims 2-3, 5-21, 37-39, Huppert et al disclose all the limitations; as set forth; for example, the flange adapted to be positioned within a preformed anterior-oblique opening, as best seen in FIG. 4” and “[w]ith respect to claims 30-36, 40, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.” However, despite the Office Action statements quoted above, no basis has been offered for the rejection of claims 3, 9, 10, 12, 13, 35, 36 and 40, which meets the requirement of 37 CFR §1.04. Which requirement states that “[i]n rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. . . . The pertinence of each reference, if not apparent, must be clearly explained, and each rejected claim specified.” (emphasis added). Therefore, claims 3, 9, 10, 12, 13, 35, 36 and 40 have not yet received a *first* action on the merits.

Conclusion

An early formal notice of allowance of claims 1-3, 8-25, 30-36, 37, 38 and 40-43 is requested. The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

If the Examiner determines that a discussion with the undersigned would expedite prosecution, he is invited to call at 972-739-6969.

Please grant any extension of time required to enter this response and charge any additional required fees, including claim fees, to our Deposit Account No. 08-1394.

Respectfully submitted,



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Dated: July 25, 2008

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Client Matter No.: PC888.00 / 31132.123
Doc. No. 194877

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Diane Sutton